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REMARKS

The Examiner objects to Figs. 2 and 14-17 as being unclear. The Examiner also objects to the drawings under 37 C.F.R. § 1.83(a) as failing to show every feature of the invention specified in the claims.

The Examiner rejects Claims 25 and 31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In addition, the Examiner rejects Claims 18, 20, 27, 29, and 30 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner also rejects Claim 31 under 35 U.S.C. § 112, sixth paragraph, as including functional language that does not include sufficient structure for achieving the specified function.

In addition, the Examiner has rejected Claims 25, 27, 29-31 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,155,684 to Bille et al. ("Bille"). The Examiner has also rejected Claims 18, 20, 22, 24, and 32-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,045,578 to Collins et al. ("Collins") in view of Bille. In addition, the Examiner has rejected Claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Collins in view of Bille, and further in view of the article to Carlos E. Martinez et al., "Effect of Pupillary Dilation on Corneal Optical Aberrations After Photorefractive Keratectomy", Archives of Ophthalmology, Vol. 116, PP. 1053-1062 (August 1998) ("Martinez").

Independent Claims 18 and 25 stand currently amended, as does dependent Claim 31. Claims 20, 27, and 29 stand currently canceled, and Claims 1-17, 19, 21, 26, and 28 stand previously canceled.

Claims 18, 22-25, and 30-34 are currently pending. The following remarks are considered by applicant to overcome each of the Examiner's outstanding rejections to current Claims 18, 22-25, and 30-34. An early Notice of Allowance is therefore requested.

I. ANY NEXT OFFICE ACTION CANNOT BE MARKED FINAL

Applicant notes that, since the current Amendment/Response includes substantive amendments to the claims and is accompanied by an RCE, any next Office Action **must** be marked as **non-final**.

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II. EXAMINER INTERVIEW

An in-person interview was held with Examiner on July 14, 2010, during which amendments above and detailed comments below were discussed. Examiner indicated that the above amendments to the drawings and the claims overcame all of the objections and rejections set forth in the current Office Action. <u>As such, Examiner indicated that all of the current objections and rejections would be withdrawn.</u>

However, Examiner did point to a new reference (i.e., U.S. Patent Application Pub. No. 2001/0053906 to Odrich et al. ("Odrich")) that Examiner believes **may** be able to be combined with other references to render some of the current claims obvious. More specifically, Examiner indicated that he may combine Odrich with Collins to reject some of the claims as being obvious. Applicant's detailed comments regarding such a possible rejection are presented below.

III. DISCUSSION WITH EXAMINER BEFORE ANY NEXT OFFICE ACTION

Applicant also notes that Examiner stated that, if he determines that the current independent claims are still not patentable after a further search and consideration, Examiner would call Applicant's attorneys before issuing any next Office Action to discuss possible claim amendments which would put the case in condition for allowance.

IV. SUMMARY OF RELEVANT LAW

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The determination of obviousness rests on whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In determining obviousness, four factors should be weighed: (1) the scope and content of the prior art, (2) the differences between the art and the claims at issue, (3) the level of ordinary skill in the art, and (4) whatever objective evidence may be present. Obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor. The Examiner carries the burden under 35 U.S.C. § 103 to establish a prima facie case of

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obviousness and must show that the references relied on teach or suggest all of the limitations of the claims.

V. OBJECTIONS TO THE DRAWINGS

On pages 2 and 7 of the current Office Action, the Examiner objects to Figs. 2 and 14-17. The Examiner also objects to the drawings under 37 C.F.R. § 1.83(a) as failing to show every feature of the invention specified in the claims. These objections are respectfully traversed and believed overcome in view of the following discussion.

A. Objection to Figs. 2 and 14-17

(1) Fig. 2

The Examiner objects to Fig. 2 as containing text which is unclear.

While Applicant respectfully asserts that the text of Fig. 2 is sufficiently clear and legible, in an effort to assuage Examiner's concerns, a Replacement Sheet with a replacement drawing for Fig. 2 has been provided in Appendix A. The numbers in the replacement Fig. 2 have been amended to increase their legibility. Therefore, Applicant respectfully asserts that Fig. 2 is in acceptable form.

(2) Figs. 14-16

Examiner asserts that Figs. 14-16 contain blurred images intended to illustrate where those images converge relative to the retina.

Figs. 14-16 are discussed in detail in paragraphs [0065]-[0067], [0072]-[0073], and [0079], respectively, as well in the paragraphs surrounding the ones specifically mentioned. As such, it is clear from the Figs. 14-16 that the vertical arrows refer to the locations of the focal points of the respective image beams in the various types of eyes. Accordingly, Applicant respectfully asserts that Figs. 14-16 are clear enough as they are, and require no further labels.

However, in an effort to provide Examiner with clear versions of Figs. 14-16, Applicant has herewith submitted Replacement Sheets in Appendix A, providing versions of Figs. 14-16 with clearly labeled focal points. Accordingly, Applicant respectfully asserts that Figs. 14-16 are now in acceptable form.

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(3) Fig. 17

Moreover, Fig. 17 shows images breaking down the generic aberrations into second- and higher-order components. While the images may not be the clearest images ever produced, they are certainly clear enough to be understood by one of ordinary skill in the art. Further, they are in fact labeled (i.e., "Overall Wavefront Aberration", "Sphera", "Cylinder", and "Higher Order Aberrations"), and one of ordinary skill in the art would understand what is being depicted based on these labels without requiring further labeling of the light areas and the shaded areas. Moreover, the images of Fig. 17 (being images and not drawings) are the best quality images that are available. However, in an attempt to assuage some of Examiner's, provide Applicant has herewith submitted a Replacement Sheet in Appendix A, providing a version of Fig. 17 with clearer labels.

Since the images of Fig. 17 are the best available, and they are certainly clear enough to be understood by one of ordinary skill in the art in view of the disclosure of the Specification without requiring additional labeling, Applicant respectfully asserts that Fig. 17 is in acceptable form.

(4) Conclusion

For all the above reasons, Applicant respectfully asserts that Figs. 2 and 14-17 are now in acceptable form. Therefore, Applicant respectfully requests Examiner withdraw the objection to Figs. 2 and 14-17.

B. Objection Under 37 C.F.R. § 1.83(a)

The Examiner asserts that the aberrometric measuring means, first and second photoablative pattern generating means, supply means, and the structural cooperation between all of these elements must be shown or the features canceled from the claims. This, however, is incorrect.

More specifically, as will be elaborated below in response to the Examiner's various 35 U.S.C. § 112 rejections, the novel aspect of the current claimed invention is **not** in the **physical** design of the excimer laser or its controller (as Examiner seems to be interpreting the thrust of the claims). Rather, the new aspect, and that which is claimed, is how the controller is **set up** to control the excimer laser.

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In other words, the physical design of a controller and an excimer laser is already well known in the art, and the claims are not drawn to any new physical design for either the laser or the controller. In fact, a specific type of Wavefront analyzer (i.e., the WASCA Wavefront analyzer) for acquiring an aberrometric map of the eye is discussed throughout the current Application. In addition, a user manual and a booklet related to the WASCA (both published shortly before the current Application's priority date) have been included in an IDS filed concurrently with this Amendment/Response (and are attached hereto in Appendixes B and C) to show the level of understanding in the art at the time the current application was filed. As such, one of ordinary skill in the art already knows how to physically construct a controller and an excimer laser in general. Thus no drawings related thereto is required by the current Application or claims thereof.

Rather, all of the novel aspects of the physical controller of the claims relate to how the controller controls an excimer laser. Thus, it is not the physical locations of the various means which are important and need to be shown. Instead, what is important is how the various means of the controller(s) operate. This is what will show one of ordinary skill in the art how to set up the controller. Consequently, just such an operational relationship for the various means of the controller(s) is depicted in the flow chart of Fig. 18. No further drawings are needed to depict how the various means and controllers of the current claims interact with one another. Thus, based on the state of the prior art relating to the physical design of controllers and excimer lasers, and the disclosure of the operational relationship between the various means of the controller(s) of the current claims which is described in the current Application and shown in Fig. 18, one of ordinary skill in the art would more than clearly understand what is being claimed and how to construct the claimed device.

Accordingly, Applicant respectfully asserts that the Examiner has failed to establish that the drawings fail to show every feature of the invention specified in the claims. Therefore, Applicant respectfully requests Examiner withdraw the objection to the drawings under 37 C.F.R. § 1.83(a) as failing to show every feature of the invention specified in the claims.

C. Examiner Interview

The above comments were discussed with Examiner during the July 14, 2010 interview, and Examiner indicated that the current amendments to the drawings and the

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claims overcame the above objections to the drawings. As such, Examiner indicated that the current objections to the drawings would be withdrawn upon filing of the above drawing and claim amendments.

VI. REJECTION OF CLAIMS 25 AND 31 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

On page 8 of the current Office Action, the Examiner rejects Claims 25 and 31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. These rejections are respectfully traversed and believed overcome in view of the following discussion.

A. Claim 25

The Examiner's rejection to Claim 25 stems from the assertion that it is unclear where the first photoablative pattern generating means is in relation to the second photoablative pattern generating means. This, however, misinterprets and/or misunderstands the language of Claim 25.

More specifically, the first and second photoablative pattern generating means of Claim 25 are part of the **first control means**. This is a means for controlling the excimer laser. As such, it is the excimer laser (a device with commonly understood parts to one of ordinary skill in the art) that has the optical components that project the photoablative pattern on the cornea. However, this is not the novel aspect being claimed in Claim 25. Rather, it is the first control means (which electronically controls the excimer laser) that is novel, and is the main subject of the disputed language of Claim 25.

As the first control means is an electronic device that controls the excimer laser, the physical location of the first control means is unimportant, so long as the first control means is somehow electronically connected to the excimer laser. A control means in general for controlling an excimer laser is commonly known in the art, and one of ordinary skill in the art knows how to physically construct a control unit in general. As such, the only enablement needed for one of ordinary skill in the art to construct the specific first control unit of Claim 25 is to know the specific functions which the first control unit must be configured to control.

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This is also the case for the first and second photoablative pattern generating means. More specifically, as with a control means in general, one of ordinary skill in the art also knows how to construct general photoablative pattern generating means, since a general photoablative pattern generating means is known in the art and not new. To clarify, the claimed photoablative pattern generating means does not actually project a photoablative pattern onto a cornea. Rather, the claimed photoablative pattern generating means generates/creates a photoablative pattern in electronic form. This electronic photoablative pattern is then supplied to the excimer laser by the supply means, the excimer laser, in turn, being the device that actually physically produces the photoablative pattern. Thus, as with the first control means of Claim 25, the actual physical locations of the first and second photoablative pattern generating means are unimportant, so long as they (as part of the first control means) are somehow electronically connected to the excimer laser (in the case of Claim 25, via the supply means). As such, the only enablement needed for one of ordinary skill in the art to construct the claimed first and second photoablative pattern generating means of Claim 25 is to know the specific functions which the first and second photoablative pattern generating means must be configured to control.

In other words, the disputed "means" of Claim 25 are one or more electronic devices with physical structures that are already known. In fact, a specific type of Wavefront analyzer (i.e., the WASCA Wavefront analyzer) for acquiring an aberrometric map of the eye is discussed throughout the current Application. In addition, a user manual and a booklet related to the WASCA (both published shortly before the current Application's priority date) have been included in an IDS filed concurrently with this Amendment/Response (and are attached hereto in Appendixes B and C) to show the level of understanding in the art at the time the current application was filed.

However, a control means or photoablative pattern generating means is meaningless, unless the **tasks** these **electronic** means must be configured to **perform/control** are defined exactly. Once these tasks have been adequately defined and described, one of ordinary skill in the art would be more than enabled to create such a defined and described control means and photoablative pattern generating means. As such, the control means and photoablative pattern generating means are sufficiently enabled by the

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more than ample description of the tasks which these physical means must be configured to control/perform.

Accordingly, Applicant respectfully asserts that Examiner has <u>failed</u> to establish that Claim 25 has failed to comply with the enablement requirement. Therefore, Applicant respectfully requests Examiner withdraw the rejection of Claim 25 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

B. Claim 31

Similarly to the Examiner's issues with claim 25, the examiner asserts that Claim 31 is not enabled because it is unclear where the first control means is in relation to the second control means.

As with the first and second photoablative pattern generating means, the physical structure of the first and second control means are generally known in the art. Thus, as stated above, the physical locations of the first and second control means are unimportant, so long as the first and second control means are somehow electronically connected to the excimer laser.

What one of ordinary skill in the art needs to know, in order to be enabled to create the first and second control means, is exactly what **tasks** these **electronic** means must be configured to **perform/control**. These tasks are defined very clearly in Claims 25 and 31. As such, the first and second control means are sufficiently enabled by the more than ample description of the tasks which these physical means must be configured to control/perform.

Accordingly, Applicant respectfully asserts that Examiner has <u>failed</u> to establish that Claim 31 does not comply with the enablement requirement. Therefore, Applicant respectfully requests Examiner withdraw the rejection of Claim 31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

C. Examient Interview

The above comments were discussed with Examiner during the July 14, 2010 interview, and Examiner indicated that the current amendments to the claims overcame the above rejection under 35 U.S.C. § 112, first paragraph. As such, Examiner indicated that the current rejection under 35 U.S.C. § 112, first paragraph, would be withdrawn upon filing of the above claim amendments.

VII. REJECTION OF CLAIMS 18, 29, AND 30 UNDER 35 U.S.C. § 112, SECOND
PARAGRAPH

On pages 3-5 and 9 of the current Office Action, the Examiner rejects Claims 18, 29, and 30 under 35 U.S.C. § 112, second paragraph, as being indefinite. These rejections are respectfully traversed and believed overcome in view of the following

A. <u>Claim 18</u>

discussion.

The Examiner asserts that steps a2) and a3) involve calculations that must be performed but are not manipulative steps of the method. As such, Examiner asserts that it is unclear how steps a2) and a3) further modify the method.

These two steps describe how the overcorrect photoablative patter is obtained. While part of each step my be mathematical in nature, the entirety of each of steps a2) and a3) is **not** merely a calculation, but rather part of the method that results in obtaining an overcorrect photoablative pattern inducing positive spherical aberration. In fact, steps a2) and a3) are part of, and thus linked to, the step a) of controlling the excimer laser unit to produce on the cornea a photoablative pattern inducing a fourth-order ocular aberration. Thus, the manipulative steps a2) and a3) are tied to a device or element (i.e., part of controlling the excimer laser to produce an over correct photoablative pattern).

In response, Examiner argues that it is not clear how steps a2) and a3) manipulate the step of obtaining or the step of controlling.

As such, Claim 18 has been currently amended to link the "acquiring and interpreting" step to "detecting a spherical aberration". In addition, the steps a2) and a3) (relating to conditional language depending upon the "detected spherical aberration" obtained during the "acquiring and interpreting" step) have also been amended to relate to a step of "supplying said excimer laser unit with an overcorrect photoablative pattern".

Accordingly, Applicant respectfully asserts that Claim 18 is now clear and definite. Therefore, Applicant respectfully requests the Examiner withdraw any rejection of Claim 18 under 35 U.S.C. § 112, second paragraph, as being indefinite.

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B. Claims 29 and 30

Examiner asserts that claims 29 and 30 do not add a new element or device to the system and that they do not alter the structural relationship between the existing elements. As such, examiner asserts that Claims 29 and 30 are indefinite. This, however, is incorrect.

More specifically, not all physical devices are defined **solely** by their structure. Occasionally, devices are also defined by the tasks that they are configured to perform. This is most often the case with electronic devices, such as controllers.

For Example, it is clear that a hand held device which displays a map of a person's current location (basically an electronic road atlas) is different from a device that calculates and displays how to get from a persons current location to a specified destination (i.e., a GPS navigation device). However, their internal physical structures may be identical. Rather, the important distinction is in how each electronic device is set up. In other words, it is the tasks that each device performs that more accurately defines the devices than their physical electronic components.

In the case of Claim 29 and 30, they further define the first control means (i.e., a physical device) by further specifying exactly what actions the first control means is configured to control. This is what distinguishes the controller of the current claims from any of the controller of the prior art. Claims 29 and 30 are not indefinite merely because they drawn to differences in the electronic configuration of a controller rather than differences in the physical configuration of a controller.

For all of the reasons above, Applicant respectfully asserts that Claims 29 and 30 are definite. Therefore, Applicant respectfully requests Examiner withdraw the rejection of Claims 29 and 30 under 35 U.S.C. § 112, second paragraph, as being indefinite.

C. Examient Interview

The above comments were discussed with Examiner during the July 14, 2010 interview, and Examiner indicated that the current amendments to the claims overcame the above rejection under 35 U.S.C. § 112, second paragraph. As such, Examiner indicated that the current rejection under 35 U.S.C. § 112, second paragraph, would be withdrawn upon filing of the above claim amendments.

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VIII. REJECTION OF CLAIM 31 UNDER 35 U.S.C. § 112, SIXTH PARAGRAPH

On page 10 of the current Office Action, the Examiner rejects Claim 31 under 35 U.S.C. § 112, sixth paragraph, as including functional language without sufficient structure for achieving the specified function. This rejection is respectfully traversed and believed overcome in view of the following discussion.

As discussed above in response to the Examiner's rejections of Claims 25 and 31 under 35 U.S.C. § 112, first paragraph, the physical structure of the first and second control means are generally known in the art. Thus, as stated above, the physical locations of the first and second control means are unimportant, so long as the first and second control means are somehow electronically connected to the excimer laser.

What one of ordinary skill in the art needs to know, in order to be enabled to create the first and second control means, is exactly what **tasks** these **electronic** means must be configured to **perform/control**. These tasks are defined very clearly in Claims 25 and 31. As such, the disclosure of the first and second control means themselves inherently provides sufficient structure for achieving the specified tasks of the first and second control means.

The above comments were discussed with Examiner during the July 14, 2010 interview, and Examiner indicated that the current amendments to the claims overcame the above rejection under 35 U.S.C. § 112, sixth paragraph. As such, Examiner indicated that the current rejection under 35 U.S.C. § 112, sixth paragraph, would be withdrawn upon filing of the above claim amendments.

Accordingly, Applicant respectfully asserts that Examiner has <u>failed</u> to establish that Claim 31 does not include sufficient structure for achieving the specified function. Therefore, Applicant respectfully requests Examiner withdraw the rejection of Claim 31 under 35 U.S.C. § 112, sixth paragraph.

IX. REJECTION OF CLAIMS 25, 27, AND 29-31 UNDER 35 U.S.C. § 102(B) BASED ON BILLE

On page 9 of the current Office Action, the Examiner rejects Claims 25, 27, and 29-31 under 35 U.S.C. § 102(b) as being anticipated by Bille. These rejections are respectfully traversed and believed overcome in view of the following discussion.

Similarly to Claim 18, amended, independent Claim 25 states, in part:

"An excimer laser unit for performing which performs cornea ablation to reduce presbyopia, comprising:

"a) first control means for controlling said excimer laser unit to form on the cornea a photoablative pattern inducing a fourth-order ocular aberration;

- a2) first photoablative pattern generating means which are activated, if the detected spherical aberration is negative, to generate an overcorrect photoablative pattern that results in an induced positive spherical aberration after treatment, the overcorrect photoablative pattern being generated by generating a photoablative pattern to correct a spherical aberration that is numerically increased in absolute value from the spherical aberration detected by said aberrometric measuring means;
- a3) second photoablative pattern generating means which are activated, if the detected spherical aberration is positive, to generate an overcorrect photoablative pattern that results in an induced positive spherical aberration after treatment, the overcorrect photoablative pattern being generated by generating a photoablative pattern to correct a spherical aberration that is opposite in sign and numerically increased in absolute value from the spherical aberration detected by said aberrometric measuring means...."

 (emphasis added).

As such, Claim 25 requires that the excimer laser (1) performs cornea ablation to reduce presbyopia, (2) actually induces a fourth-order ocular aberration, and (3) results in an induced spherical aberration after treatment.

Examiner asserts that Claim 25 is anticipated by Bille. However, the misinterprets the teachings of Bille.

More specifically, even under Examiner's interpretation of Bille, the system of Bille only treats astigmatic disorders. As explained above in relation to Claim 18, astigmatism is very different from presbyopia. In fact, Bille, as Williams, **never** even mentions presbyopia. For this reason alone, Bille <u>fails</u> to anticipate Claim 25.

In addition, Examiner has completely <u>failed</u> to indicate any portion of Bille whatsoever that actually discloses any element (inherent or otherwise) which controls an excimer laser to form on the cornea a photoablative pattern that actually **induces a fourth-order ocular aberration**. Rather, all that Bille discloses is a method and apparatus which can be used to **determine** higher order refractive error (aberrations) such as spherical (i.e., fourth order) aberration. Bille, Col. 4, Lns. 5-23 (cited by Examiner). This does not mean that a fourth-order ocular aberration is actually **induced**.

Moreover, Bille teaches to **reduce** the aberrations of the eye after the treatment to **zero**. As discussed above in relation to Claim 18, such a teaching is very **different** from the apparatus of Claim 25, which induces spherical aberration, **resulting in** an induced spherical aberration <u>after</u> treatment.

In response, Examiner asserts that Applicant fails to argue that Bille's system is not capable of performing the aberration of Claim 25. Examiner asserts that the system of Claim 25 does not contain elements or structural cooperation that uniquely enables the device of Claim 25 to induce a fourth order aberration. However, this is incorrect.

More specifically, the control means is what uniquely enables the device of Claim 25 to generate an overcorrect photoablative pattern that results in an induced positive spherical aberration after treatment. While the excimer laser of Bille could be used to surgically modify a patient eye so as to induce a positive spherical aberration after treatment, Bille discloses no device whatsoever that qualifies as the specified control means of Claim 25.

Examiner asserts that the system of Claim 25 simply contains a control means capable of programming an excimer laser. However, this is either a mischaracterization or misinterpretation of Claim 25. As such, in order to better clarify Claim 25, it has been currently amended.

In particular, Claim 25 has been amended to specify that the first photoablative pattern generating means generates an overcorrect photoablative pattern that results in an induced positive spherical aberration after treatment, when the detected spherical aberration is negative. The first photoablative pattern generating means generates this overcorrect photoablative pattern by generating a photoablative pattern to

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correct a spherical aberration that is numerically increased in absolute value from the spherical aberration detected by said aberrometric measuring means.

Similarly, the second photoablative pattern generating means generates an overcorrect photoablative pattern that results in an induced positive spherical aberration after treatment, when the detected spherical aberration is positive. The second photoablative pattern generating means generates this overcorrect photoablative pattern by generating a photoablative pattern to correct a spherical aberration that is opposite in sign and numerically increased in absolute value from the spherical aberration detected by said aberrometric measuring means.

As such, the first control means, the first photoablative pattern generating means, and the second photoablative pattern generating means are all specifically defined by the tasks they perform. While the laser of Bille may be capable of surgically altering an eye to result in an induced **positive spherical aberration after treatment**, this is not sufficient to anticipate Claim 25. Rather, the important structural aspect of Claim 25 is the specified controller (i.e., the first control means) and how it is configured. There is no controller disclosed in Bille which can perform the tasks specified in Claim 25 without having to be altered as disclosed in the current application. As such, Bille <u>fails</u> to disclose every element of Claim 25 as specified above. Bille also <u>fails</u> to teach or suggest the above elements of Claim 25, since the only suggestion for modifying the controller of Bille according to the parameters of Claim 25 is the current Application itself.

Examiner asserts that Bille's system is capable of performing the method claimed, whether or not there is suggestion to do so. However, this is incorrect.

Without the specific controller (i.e., first control means) of Claim 25, it is impossible for the device of Billie to perform the claimed method. In addition, Claim 25 relates to a device, and not a method. As stated above, Bille <u>fails</u> to teach or suggest the specific controller (i.e., first control means) required by Claim 25. Contrary to Examiner's assertion, Bille <u>must</u> either (1) disclose the specified controller (i.e., first control means) of Claim 25 which includes **both** the first and second photoablative pattern generating means, or (2) suggest such a specific controller with the specific photoablative pattern generating means. Since Bille <u>fails</u> to do either (1) or (2) above, it is impossible for Bille to either anticipate or render obvious Claims 25.

The above comments were discussed with Examiner during the July 14, 2010 interview, and Examiner indicated that the current amendments to the claims overcame the above rejection under 35 U.S.C. § 102(b). As such, Examiner indicated that the current anticipation rejection would be withdrawn upon filing of the above claim amendments.

Accordingly, for all the reasons above, Applicant respectfully asserts that Examiner has failed to establish a prima facie case of anticipation of independent Claim 25, and corresponding Claims 29-31 because they are all ultimately dependant from independent Claim 25. Therefore, Applicant respectfully requests that Examiner remove the rejection of Claims 25 and 29-31 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,155,684 to Bille et al.

X. REJECTION OF CLAIMS 18, 22-24, AND 32-34 UNDER 35 U.S.C. § 103(A) BASED ON COLLINS IN VIEW OF BILLE

On page 11 of the current Office Action, the Examiner rejects Claims 18, 22-24, and 32-34 under 35 U.S.C. § 103(a) as being unpatentable over Collins in view of Bille. These rejections are respectfully traversed and believed overcome in view of the following discussion.

A. Claims 18 and 22-24

Amended, tndependent Claim 18 states, in part:

"A method of controlling an excimer laser unit to perform cornea ablation to reduce presbyopia, the method comprising the step of:

- a1) acquiring and interpreting an aberrometric map of the eye indicating the visual defects of the eye, said visual defects comprising secondorder visual defects including hypermetropia, astigmatism, and myopia, and higher-order visual defects including spherical aberration, thereby detecting a spherical aberration;
- a2) if the detected spherical aberration is negative, supplying said excimer laser unit with an overcorrect photoablative pattern that results in an induced positive spherical

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aberration after treatment, the overcorrect photoablative pattern being obtained by obtaining a photoablative pattern to correct a spherical aberration that is increased numerically in absolute value from the detected spherical aberration;

a3) if the detected spherical aberration is positive, supplying said excimer laser unit with an overcorrect photoablative pattern that results in an induced positive spherical aberration after treatment, the overcorrect photoablative pattern being obtained by obtaining a photoablative pattern to correct a spherical aberration that is opposite in sign and increased numerically in absolute value from the detected spherical aberration..." (emphasis added).

As such, Claim 18 is specifically drawn to a method of reducing **presbyopia**. However, neither Collins nor Bille relates to treating presbyopia. In fact, Collins is specifically drawn to treating myopia and hyperopia.

Examiner asserts that presbyopia results in myopic vision, and therefore its correction may be similar to that of myopia. However, this is a blind assertion by Examiner with no support whatsoever.

In fact, as stated in previous responses, paragraphs [0085], [0087], and [0091] of the current Application explain:

"[0085] Correction of myopia, hypermetropia and astigmatism is based on laser ablation techniques employing photoablative patterns designed to eliminate the cylinder and sphere, i.e. to eliminate second-order aberrations.

"[0087] Higher-order aberrations are normally left unchanged. More specifically, third-order aberrations are normally associated with "coma" visual defects, while fourth-order aberrations, and particularly the spherical aberration measured by the coefficient of Zernike's polynomial Z.sub.4.sup.0, are partly related to transient accommodation phenomena.

"[0091] **Presbyopia**, on the other hand, is a visual defect which consists in diminished accommodation power of the eye to focus on near objects, is mainly encountered in

adults, and is due to a loss of elasticity of the crystalline

lens. Unlike myopia, hypermetropia and astigmatism, presbyopia is therefore not a refractive defect and, unlike the cases described above, is not easy to solve using photoablative techniques." (emphasis added).

Thus, presbyopia is due to a loss of elasticity of the crystalline lens.

Whereas Collins teaches that myopia typically develops because the axial length of the eye grows to be longer than the focal length of the optical components of the eye, that is, the eye grows too long. Collins, Col. 1, Lns. 17-20. Collins also teaches that hyperopia typically develops because the axial length of the eye is too short compared with the focal length of the optical components of the eye, that is, the eye does not grow enough. Collins, Col. 1, Lns. 20-23. As such, the methods of Collins relate to either promoting or deterring axial eye growth via the creation of a spherical aberration.

Thus, presbyopia (caused by a loss of elasticity of the crystalline lens) is different from myopia or hypermetropia (caused by an axial length of the eye that is either too long or too short). As such, it is certainly **not obvious** to expect a treatment designed to control the axial growth of an eye (i.e., Collins's treatments for myopia and hypermetropia) to also be able to correct a loss of elasticity of the crystalline lens (i.e., the cause of prespyopia).

As such, it is **impossible** to combine the cited references in such a way to arrive at a method for treating presbyopia.

In addition, the method of Claim 18 requires steps that are neither taught nor suggested by either Collins or Bille. More specifically, as stated above, Claim 18 requires supplying an excimer laser unit with an overcorrect photoablative pattern that is obtained by obtaining a photoablative pattern to correct a spherical aberration that is increased numerically in absolute value from a detected spherical aberration of an eye, when the detected spherical aberration is negative. As stated above, Claim 18 also requires supplying an excimer laser unit with an overcorrect photoablative pattern that is obtained by obtaining a photoablative pattern to correct a spherical aberration that is opposite in sign and increased numerically in absolute value from a detected spherical aberration of an eye, when the detected spherical aberration is positive.

While Collins teaches inducing a spherical aberration in an eye, any method of inducing such a spherical aberration would involve steps of inducing the aberration based

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on the axial length of the eye. Thus, any obvious method of Collins that might involve supplying an excimer laser unit with a photoablative patter would have obtained that photoablative pattern based on the axial length of the eye, and <u>not</u> based on the method of obtaining the overcorrect photoablative patter of Claim 18. As such, any combination of the method of Collins with the excimer laser of Bille <u>fails</u> to disclose the method of Claim 18 set forth above.

Accordingly, for all the reasons above, Applicant respectfully asserts that Examiner has failed to establish a prima facie case of anticipation of independent Claim 18, and corresponding Claims 22-24 because they are all ultimately dependant from independent Claim 18. Therefore, Applicant respectfully requests that Examiner remove the rejection of Claims 18 and 22-24 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,045,578 to Collins et al. in view of U.S. Patent No. 6,155,684 to Bille et al.

B. Claims 32-34

Similarly to Claim 18, amended, independent Claim 32 states:

"A method of reducing presbyopia, comprising the step of:

"forming on the cornea a photoablative pattern inducing a fourth-order ocular aberration, resulting in a fourth-order ocular aberration after treatment." (emphasis added).

As such, Claim 32 is specifically drawn to a method of reducing **presbyopia**. However, as discussed above, neither Collins nor Bille relates to treating presbyopia. In fact, Collins is specifically drawn to treating myopia and hyperopia.

Examiner asserts that presbyopia results in myopic vision, and therefore its correction may be similar to that of myopia. However, this is a blind assertion by Examiner with no support whatsoever.

In fact, as stated in previous responses, paragraphs [0085], [0087], and [0091] of the current Application explain:

"[0085] Correction of myopia, hypermetropia and astigmatism is based on laser ablation techniques employing photoablative patterns designed to eliminate the cylinder and sphere, i.e. to eliminate second-order aberrations.

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"[0087] Higher-order aberrations are normally left unchanged. More specifically, third-order aberrations are normally associated with "coma" visual defects, while fourth-order aberrations, and particularly the spherical aberration measured by the coefficient of Zernike's polynomial Z.sub.4.sup.0, are partly related to transient accommodation phenomena.

"[0091] Presbyopia, on the other hand, is a visual defect which consists in diminished accommodation power of the eye to focus on near objects, is mainly encountered in adults, and is due to a loss of elasticity of the crystalline lens. Unlike myopia, hypermetropia and astigmatism, presbyopia is therefore not a refractive defect and, unlike the cases described above, is not easy to solve using photoablative techniques." (emphasis added).

Thus, presbyopia is due to a loss of elasticity of the crystalline lens. Whereas Collins teaches that myopia typically develops because the axial length of the eye grows to be longer than the focal length of the optical components of the eye, that is, the eye grows too long. Collins, Col. 1, Lns. 17-20. Collins also teaches that hyperopia typically develops because the axial length of the eye is too short compared with the focal length of the optical components of the eye, that is, the eye does not grow enough. Collins, Col. 1, Lns. 20-23. As such, the methods of Collins relate to either promoting or deterring axial eye growth via the creation of a spherical aberration.

Thus, presbyopia (caused by a loss of elasticity of the crystalline lens) is different from myopia or hypermetropia (caused by an axial length of the eye that is either too long or too short). As such, it is certainly **not obvious** to expect a treatment designed to control the axial growth of an eye (i.e., Collins's treatments for myopia and hypermetropia) to also be able to correct a loss of elasticity of the crystalline lens (i.e., the cause of prespyopia).

As such, it is **impossible** to combine the cited references in such a way to arrive at a method for treating presbyopia.

Accordingly, Applicant respectfully asserts that Examiner has failed to establish a prima facie case of obviousness of independent Claim 32, and corresponding Claims 33 and 34 because they are all ultimately dependent from independent Claim 32. Therefore, Applicant respectfully requests that Examiner remove the rejection of

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Claims 32-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,045,578 to Collins et al. in view of U.S. Patent No. 6,155,684 to Bille et al.

C. Examiner Interview

The above comments were discussed with Examiner during the July 14, 2010 interview, and Examiner indicated that the current amendments to the claims overcame the above rejection under 35 U.S.C. § 103(a). As such, Examiner indicated that the above obviousness rejection would be withdrawn upon filing of the above claim amendments.

XI. REJECTION OF CLAIM 23 UNDER 35 U.S.C. § 103(A) BASED ON COLLINS IN VIEW OF BILLE AND MARTINEZ

On page 12 of the current Office Action, the Examiner rejects Claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Collins in view of Bille and Martinez. These rejections are respectfully traversed and believed overcome in view of the following discussion.

Claim 23 is ultimately dependent from independent Claim 18. As Claim 18 is allowable, so must be Claim 23. Accordingly, Applicant respectfully asserts that Examiner has failed to establish a prima facie case of obviousness of Claim 23. Therefore, Applicant respectfully requests that Examiner remove the rejection of Claim 23 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,045,578 to Collins et al. in view of U.S. Patent No. 6,155,684 to Bille et al., and further in view of the article to Carlos E. Martinez et al., "Effect of Pupillary Dilation on Corneal Optical Aberrations After Photorefractive Keratectomy", Archives of Ophthalmology, Vol. 116, PP. 1053-1062 (August 1998).

XII. NEW ODRICH REFERENCE

As stated above, However, Examiner did point to a new reference (i.e., U.S. Patent Application Pub. No. 2001/0053906 to Odrich et al. ("Odrich")) that Examiner believes may be able to be combined with other references to render some of the current claims obvious. More specifically, Examiner indicated that he may combine Odrich with

Collins to reject some of the claims as being obvious. Any such rejection is respectfully traversed and believed overcome in view of the following discussion.

Independent Claim 18 states, in part:

- a2) if the detected spherical aberration is negative, supplying said excimer laser unit with an overcorrect photoablative pattern that results in an induced fourth-order positive spherical aberration after treatment, the overcorrect photoablative pattern being obtained by obtaining a photoablative pattern to correct a fourth-order spherical aberration that is increased numerically in absolute value from the detected fourth-order spherical aberration;
- a3) if the detected spherical aberration is positive, supplying said excimer laser unit with an overcorrect photoablative pattern that results in an induced fourth-order positive spherical aberration after treatment, the overcorrect photoablative pattern being obtained by obtaining a photoablative pattern to correct a fourth-order spherical aberration that is opposite in sign and increased numerically in absolute value from the detected fourth-order spherical aberration; and

Similarly, independent Claim 25 states, in part:

- a2) first photoablative pattern generating means which are activated, if the detected spherical aberration is negative, to generate an overcorrect photoablative pattern that results in an induced fourth-order positive spherical aberration after treatment, the overcorrect photoablative pattern being generated by generating a photoablative pattern to correct a fourth-order spherical aberration that is numerically increased in absolute value from the fourth-order spherical aberration detected by said aberrometric measuring means;
- a3) second photoablative pattern generating means which are activated, if the detected spherical aberration is positive, to generate an overcorrect photoablative pattern that results in an induced fourth-order positive spherical aberration after treatment, the

overcorrect photoablative pattern being generated by generating a photoablative pattern to correct a fourth-order spherical aberration that is opposite in sign and numerically increased in absolute value from the fourth-order spherical aberration detected by said aberrometric measuring means;

Independent Claim 32 also states, in part:

forming on the cornea a photoablative pattern inducing a fourth-order ocular aberration, resulting in a fourth-order ocular aberration after treatment.

Thus, each independent claim requires an induced **fourth-order** aberration <u>after treatment</u>. Claims 18 and 25 further require that this induced **fourth-order** aberration <u>after treatment</u> is a spherical aberration.

While Collins discusses altering the spherical aberration of an eye (see Collins, Col. 2, Lns. 65-67), Collins never discusses the order of the spherical aberration. A spherical aberration may be third-order, fourth-order, fifth-order, etc. Thus, a disclosure generically discussing spherical aberrations is insufficient to teach or suggest the required fourth-order aberration <u>after treatment</u> of the independent claims of the current Application. As such, Collins <u>fails</u> to teach or suggest an induced fourth-order aberration <u>after treatment</u>, as required by independent Claims 18, 25, and 32.

Odrich appears to be even less instructive than Collins. In particular, while Odrich discloses ablating corneal tissue from an eye so that the optical zone of the corneal surface defines an aspheric shape to mitigate the presbyopia, Odrich never discloses that this aspheric shape also means that there is a **spherical aberration** induced on the cornea. In other words, Examiner has provided **no** information whatsoever that links an aspheric corneal surface shape to a spherical aberration, let alone to a **fourth-order** spherical aberration. Thus, the aspheric corneal surface shape disclosed in Odrich does **not necessarily** mean that a **fourth-order** aberration has been induced on the cornea **after treatment**.

Applicant respectfully notes that the MPEP contains clear instructions on establishing inherency. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior

art." MPEP § 2112 (quoting Ex parte Levy, 17 USPQ2d 1451, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)) (internal quotations omitted). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP § 2112 (citing In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993)) (emphasis in original). "Also, '[a]n invitation to investigate is not an inherent disclosure' where a prior art reference 'discloses no more than a broad genus of potential applications or its discoveries." MPEP § 2112 (quoting Metabolife Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1367 (Fed. Cir. 2004)). "A prior art reference that discloses a genus still does not inherently disclose all species within that broad category' but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species." MPEP § 2112 (quoting Metabolife Labs., Inc., 370 F.3d at 1367).

As such, to reject the current claims as being obvious over Odrich in view of Collins, the Examiner must prove that the aspheric corneal shape in Odrich and the "spherical aberration" in Collins are necessarily fourth-order spherical aberrations. In absence of such proof it is impossible for Examiner to establish a *prima facie* case of obviousness of any of the current claims over Odrich in view of Collins..

In addition, Odrich made the observation that an initial ablation profile (designed to produce a spherical surface to correct for hyperopia) lead to an aspherical surface because of filling and healing. As such, Odrich provides a method to compensate for that healing effects by designing more ablation where more filing/healing is expected to get rid of the aspheric shape. Further, Odrich knows that a bi-/multi-focal ablation is supportive for eyes with presbyopia, and they address a first zone to correct for near vision a second zone to correct for far vision. For example, in Fig. 15, Odrich simply leaves out a central zone from correction (since the mid/peripheral zone appears as a hypeopic correction, this will lead to a central far vision zone and a peripheral near vision zone).

Odrich makes use of a side effect of the healing, which is that the refilling is not uniform but depends on the distance from the center of the ablation. Therefore, Odrich introduced different grades of under/over correction for hyperopic treatments in different zones leading to a wanted multifocality supportive for presbyopia.

However, Odrich does **not** teach that introducing a specific higher fourth-order aberration (i.e., especially a z40 spherical aberration shape — introducing a smooth change in local refraction from near vision in the center to far or hyperfar vision in the periphery following a parabolic local refraction-vs-radius function which is a consequence of the z40 profile of the current invention) is supportive for presbyopia. Rather, Odrich discloses a **generic** multifocality / asphericity (they accept the smoothing in ablation depth that occurs because of the healing but don't intentionally address such a smooth refraction-vs-radius profile).

Odrich also does **not** teach how to manipulate the input of a higher-order-aberration-correcting-device to introduce the wanted four-order spherical aberration (e.g., z40 spherical aberrations). Instead, Odrich leaves out a zone from ablation or corrects a given ablation profile by a loss/refilling ratio.

Furthermore, as requested by Examiner, Applicants would like to clarify what is meant by "after treatment". In particular, the current Application assumes to use a refractive laser that already implements methods to compensate for the healing process so as to achieve a refraction and higher-order aberration corrected result after healing. In this sense, the disclosures of Odrich, as being known prior art, have already been taken into account. Thus, the current invention achieves a result after healing that is not compensating all aberration, rather results in the claimed fourth-order spherical aberration. In this sense, "after treatment" means the state after regression/healing has been finished, and a final, stable state of the eye is reached (i.e., the patient uses his eyes with this induced fourth-order aberration in the patient's further life).

Thus, as with Collins, Odrich also <u>fails</u> to teach or suggest an induced **fourth-order** aberration <u>after treatment</u>, as required by independent Claims 18, 25, and 32.

Accordingly, Applicant respectfully asserts that Examiner cannot establish a prima facie case of obviousness of independent Claims 18, 25, or 32, or any of the claims which depend therefrom, based on U.S. Patent Application Pub. No. 2001/0053906 to Odrich et al. in view of U.S. Patent No. 6,045,578 to Collins et al.

Based upon the above remarks, Applicant respectfully requests reconsideration of this application and its early allowance. Should the Examiner feel that a

telephone conference with Applicant's attorney would expedite the prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,

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